

In re Application of: Shih *et al*
Serial No.: 09/431,519
Filed: November 1, 1999

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application (note that amendments are **highlighted in bold**):

Claim Listing

Claims 1-42 (canceled)

Claim 43. (currently amended) An anabolic implant composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release formulation consisting **essentially** of zeranol **and a diluent**, and (ii) a controlled-release formulation consisting **essentially** of zeranol and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

Claim 44. (previously presented) The implant composition of claim 43, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:25 in said composition.

Claim 45. (previously presented) The implant composition of claim 43, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:10 in said composition.

Claim 46. (previously presented) The implant composition of claim 43, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:3 to 1:8 in said composition.

Claim 47. (previously presented) The implant composition of claim 43, wherein said composition is subcutaneously injectable in said cattle.

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Claim 48. (currently amended) The implant composition of claim 43, wherein **said** zeranol comprises from about 50 wt.% to about 95 wt.% of said composition based on a total weight percentage basis.

Claim 49. (currently amended) The implant composition of claim 43, wherein **said** zeranol comprises from about 60 wt.% to about 80 wt.% of said composition based on a total weight percentage basis.

Claim 50. (currently amended) The implant composition of claim 43, wherein **said** -immediate-controlled-release formulation additionally contains a diluent.

Claim 51. (currently amended) The implant composition of claim 50, wherein **said** diluent of said controlled-release formulation is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

Claim 52. (currently amended) The implant composition of claim 51, wherein **said** diluent of said controlled-release formulation is lactose.

Claim 53. (previously presented) The implant composition of claim 43, wherein **said** controlled-release agent is selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

Claim 54. (previously presented) The implant composition of claim 53, wherein **said** controlled-release agent is poly(D,L-lactide-co-glycolide).

Claim 55. (previously presented) The implant composition of claim 53, wherein **said** controlled-release agent is ethyl cellulose.

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Claim 56. (previously presented) The implant composition of claim 43, wherein said controlled-release agent comprises from about 1.0 wt.% to about 8.0 wt.% based on the total weight of said implant composition.

Claim 57. (previously presented) The implant composition of claim 43, further comprising a bulking agent, binder, excipient, tabletting agent, colorant and combinations thereof.

Claim 58. (currently amended) An anabolic implant composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release formulation with an anabolic agent consisting essentially of zeranol and a diluent, and (ii) a controlled-release formulation with an anabolic agent consisting essentially of zeranol, a diluent, and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

Claim 59. (previously presented) The implant composition of claim 58, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:25 in said composition.

Claim 60. (previously presented) The implant composition of claim 58, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:10 in said composition.

Claim 61. (previously presented) The implant composition of claim 58, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:3 to 1:8 in said composition.

Claim 62. (previously presented) The implant composition of claim 58, wherein said composition is subcutaneously injectable in said cattle.

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Claim 63. (previously presented) The implant composition of claim 58, wherein said zeranol comprises from about 50 wt.% to about 95 wt.% of said composition based on a total weight percentage basis.

Claim 64. (previously presented) The implant composition of claim 58, wherein said zeranol comprises from about 60 wt.% to about 80 wt.% of said composition based on a total weight percentage basis.

Claim 65. (currently amended) The implant composition of claim 58, wherein said diluent of said immediate-release formulation and said diluent of said controlled release formulation are individually selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof and contains a diluent.

Claim 66. (Canceled)

Claim 67. (currently amended) The implant composition of claim ~~66~~ 65, wherein said diluent of said immediate-release formulation and said diluent of said controlled release formulation are both is-lactose.

Claim 68. (currently amended) The implant composition of claim ~~58~~ 65, wherein said controlled-release agent is selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

Claim 69. (currently amended) The implant composition of claim ~~58~~ 68, wherein said controlled-release agent is poly(D,L-lactide-co-glycolide).

Claim 70. (currently amended) The implant composition of claim ~~58~~ 68, wherein said controlled-release agent is ethyl cellulose.

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Claim 71. (previously presented) The implant composition of claim 43, wherein said controlled-release agent comprises from about 1.0 wt.% to about 8.0 wt.% based on the total weight of said implant composition.

Claim 72. (previously presented) The implant composition of claim 43, further comprising a bulking agent, binder, excipient, tabletting agent, colorant and combinations thereof.

Claim 73. (New) The implant composition of claim 43, wherein said diluent of said immediate-release formulation is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

Claim 74. (New) The implant composition of claim 73, wherein said diluent of said immediate-release formulation is lactose.

Claim 75. (New) An anabolic implant composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release formulation consisting essentially of zeranol and lactose, and (ii) a controlled-release formulation consisting essentially of zeranol, lactose, and poly(D,L-lactide-co-glycolide), wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

Claim 76. (New) An anabolic implant composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release formulation consisting essentially of zeranol and lactose, and (ii) a controlled-release formulation consisting essentially of zeranol, lactose, a suitable plasticizer and ethyl cellulose, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

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Claim 77 (New) The implant composition of claim 76 wherein the suitable plasticizer is triacetin.